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# Summary of chloramine-T human food safety research conducted at the Upper Midwest Environmental Sciences Center (UMESC)

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## Introduction

External flavobacteria infections are predominant diseases on cultured fish and are responsible for substantial production losses on federal, state, and commercial hatcheries. Chloramine-T (Chl-T) is a chemical effective in reducing fish mortalities caused by external flavobacteria. Legal use of Chl-T as a therapeutic drug in fish culture depends on approval by the U.S. Food and Drug Administration (FDA). The FDA requires data in the following four technical sections before a drug can be approved: 1) animal safety, 2) efficacy, 3) environmental safety, and 4) human food safety. Although the UMESC has contributed data regarding animal safety, efficacy, and environmental safety, the UMESC has led the efforts to fulfill FDA's data criteria in the human food safety technical section.

Determined Chl-T metabolites with radioactive chloramine-T

**1990 - 1992**

**1995**

FDA declared p-TSA the marker residue for chloramine-T

Developed a new method specific for p-TSA

**1997**

accuracy precision

**PASSED**

sensitivity robustness specificity

**2000**

Evaluated method with FDA criteria for a determinative method

Determined the depletion of p-TSA from hybrid striped bass, yellow perch, and rainbow trout

**2001 - 2002**

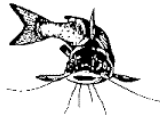
**2000 - 2001**

Bridged old method to the new method specific for p-TSA

**2000 - 2002**

FDA developed confirmatory method



## Conclusion

The UMESC's efforts with Chl-T human food safety research have culminated in the following pivotal outcomes: 1) declaration of a marker residue (p-TSA) for Chl-T; 2) development of a regulatory method package (determinative and confirmatory methods) for p-TSA; and 3) determination of p-TSA depletion from three species of fish exposed to Chl-T, each from a cold, cool, or warm water temperature grouping. Data from these outcomes will ultimately allow the FDA to establish a withdrawal time for exposed fish ensuring that total Chl-T residues reach safe concentrations before fish are made available for human consumption.